

REMARKS

Applicants amend claims 1, 15, 31, 49 and 50, cancel claims 2, 3, and 32, and add new claims 51-57, as shown above in the listing of the claims. Support for the amendments and the new claims can be found throughout the specification, for example, at page 8, line 30 to page 9, line 15. Thus, no new matter is added. As discussed below, the application is now in condition for allowance. Reconsideration and allowance are respectfully requested.

Rejections Under 35 U.S.C. 102

The Office Action rejects claims 49-50, 1, 3-4, 8, 10-12, 19-21, 27-28 and 31-32 as being anticipated by U.S. Patent No. 5,601,883 of Yamazaki.

Claim 1, as amended, recites a method of treating an inner surface of a tubular article having a lumen by generating a gaseous plasma within a spatially-localized region of space by electron cyclotron resonance and exposing at least a portion of *an inner surface of the lumen* of the tubular article to the plasma for a selected time period to treat that surface. This is followed by coating the treated surface with a selected material.

Yamazaki discloses a chemical vapor deposition method for coating plastic articles, such as, gear-wheels, screws, buttons or toy parts, with crystalline carbon films. More specifically, an article of interest is placed in an evacuated chamber into which a non-productive gas, e.g., hydrogen, helium or argon, is introduced. The article is then subjected to a plasma generated in the gas by microwave energy (2.45 GHz) and a magnetic field (2 K Gauss), so as to clean the articles. In addition, C₂H₂, C₂H₄ and/or CH₄ and a large amount of hydrogen are introduced into the chamber such that the pressure in the chamber is raised to about 0.1 to 300 Torr. The gases are excited by the microwave energy to generate a mixed resonance therein, and cause deposition of carbon on the exposed surfaces of the article.

Yamazaki does not teach utilizing an ECR plasma to treat a lumen of a tubular article followed by coating with a selected material. In fact, Yamazaki is not concerned with treating tubular articles with ECR plasma, much less treating the lumens of such articles. Rather, as

discussed above, Yamazaki employs an ECR plasma to clean *external* surfaces of non-tubular articles, such as gear wheels, buttons, or toy parts.

Thus, amended claim 1 distinguishes patentably over Yamazaki.

Because claim 1, as amended, incorporates the features of original claim 2, and the Office Action rejects claim 2 as being obvious in view of the combined teachings of Yamazaki and U.S. Patent No. 5,914,115 of Subramanian, this rejection will be addressed below with respect to the amended claim 1.

As noted above, Yamazaki does not teach treating the luminal surfaces of tubular articles with an ECR plasma. Further, Subramanian does not bridge the shortcomings of Yamazaki. Subramanian describes a method for covalently attaching therapeutic coatings to exposed surfaces of medical devices. More specifically, in Subramanian's methods, a surface of the medical device is contacted with a *glow discharge plasma* to functionalize the surface with thermochemically reactive groups covalently bound to the surface. The functionalized surface is then contacted with a bioactive agent, such as, an antithrombogenic agent, to cause covalent bonding between the agent and the reactive groups, thereby generating a therapeutic coating.

In contrast to Subramanian's glow discharge for functionalizing a surface, the claimed invention employs an ECR plasma for treating a surface of interest. Moreover, although Subramanian describes treating surfaces of tubular articles, such as catheters, with a glow discharge, it fails to teach or suggest treating the lumens of such articles. In fact, it is difficult to generate a glow discharge within the lumen of a tubular article, especially a small diameter lumen, because of plasma losses to the lumen's wall.

In addition, Subramanian provides no motivation for replacing its glow discharge plasma with an ECR plasma recited in Yamazaki. Likewise, Yamazaki provides no motivation because it utilizes an ECR plasma only for cleaning a surface of interest and does not teach or suggest employing the ECR plasma for functionalizing that surface. In fact, Yamazaki recites that when reactive gases are introduced into the chamber in which an article of interest is located "the resonance is changed from ECR to MCR (Mixed Cyclotron Resonance)." Hence, even if one

assumes that Subramanian's teachings provide an incentive to look for alternative methods for functionalizing an article's surface – which it does not since it does not consider a glow discharge as deficient for achieving its goal – Yamazaki would not present an ECR plasma as such an alternative, as it does not teach that it can be utilized for functionalizing a surface.

Thus, claim 1, as amended, distinguishes over the combined teachings of Yamazaki and Subramanian, as well.

Rejections of claims 2, 3 and 32 are moot as these claims are canceled. Claims 4, 8, 10-12, 19, 32, 27, 28 and 31 depend either directly or indirectly on claim 1, and hence are also patentable.

Claim 49, as amended, recites a method of *selectively* treating an outer surface of a tubular article having a lumen by placing a selected portion of the tubular article in a treatment zone, and applying a magnetic field having a selected strength to the treatment zone. A gas is introduced into a volume of the treatment zone so as to be in contact with an outer surface of the article. This is followed by irradiating the gas with electromagnetic radiation having a frequency selected to be substantially equal to electron cyclotron frequency at the magnetic field strength so as to ionize the gas and create a plasma in contact with the outer surface *without* being in contact with an inner surface of the lumen so as to treat the article's outer surface *without* treating its inner surface.

Yamazaki does not teach *selectively* treating an outer surface of a tubular article having a lumen with ECR plasma *without* treating the lumen's surface, i.e., the tubular article's internal surface. In fact, Yamazaki discloses coating articles, such as gears and screws, with a crystalline carbon film, and not elongated tubular articles, and especially not such tubular articles having a lumen. In addition, Yamazaki does not recognize the need for a method of selectively treating a tubular's article outer surface without treating its inner surface, nor does it teach such a method.

Hence, claim 49 distinguishes patentably over Yamazaki.

Claim 50, as amended, recites a method of treating an inner surface of a lumen of each of a plurality of tubular articles by generating a gaseous plasma within a spatially-localized region of space by electron cyclotron resonance, and simultaneously exposing a portion of an inner surface of each of the articles to the plasma for a selected time period to treat these surfaces. The treated surfaces are then coated with a selected material.

The arguments presented above with respect to amended claim 1 apply with equal force to establish that amended claim 50 is also patentable. In particular, as discussed in detail above, Yamazaki does not teach or suggest treating the inner surface of a tubular article with ECR plasma.

In Paragraph 5, the Office Action rejects claims 16-17 as being anticipated, or being obvious, over the teachings of Yamazaki. Claim 16 depends on claim 1, and claim 17 depends on claim 16. Hence, both claims incorporate the patentable features of claim 1, and accordingly, distinguish patentably over Yamazaki for the reasons provided above.

In Paragraph 6, the Office Action rejects claims 5-7, 13-14 and 18 as being obvious in view of Yamazaki.

These claims depend either directly or indirectly on claim 1 and hence distinguish patentably over Yamazaki for the reasons presented above with respect to claim 1.

In Paragraph 7, the Office Action rejects claims 2, 15, 21-28 and 32 as being unpatentable over Yamazaki in view of Subramanian, and optionally considering Kieser and Wilhelm as well.

Claims 2 and 32 are canceled, and hence their rejections will not be addressed. Claim 15 is amended to depend on claim 1. And claims 21-28 depend either directly or indirectly on claim 1. Hence, claims 15, 21-28 incorporate the features of claim 1, and more specifically, treating an inner surface of the lumen of a tubular article by its exposure to an ECR gaseous plasma. As discussed above, Yamazaki and Subramanian, neither individually nor combined,

teach or suggest treating an inner surface of a tubular article's lumen with ECR plasma followed by coating the treated surface with a selected material.

Moreover, Wilhelm and Kieser do not bridge the shortcomings of Yamazaki and Subramanian in teaching material features of claim 1, and consequently those of dependent claims 15 and 21-28. Both Wilhelm and Kieser describe methods for direct deposition of a coating material from a plasma onto a surface, and not a two-step process recited in claim 1, which includes treating the surface with ECR plasma and, in a separate step, coating the treated surface

In Paragraph 8, the Office Action rejects claims 21-24 and 26-28 as being obvious over Yamazaki in view of Subramanian, optionally considering Kieser or Wilhelm, and further in view of U.S. Patent No. 4,927,676 of Williams or U.S. Patent No. 5,942,277 of Makker or U.S. Patent No. 5,486,357 of Narayanan.

Each of the claims 21-24 depends on claim 1, and further recites coating materials for coating the surface of the tubular's article's lumen after its treatment with an ECR plasma. Claim 26 depends on claim 1, and further recites that the coating material is selected to have cell growth properties, and claims 27 and 28 depend indirectly on claim 1 (via claim 4), and recite different gases suitable for generating an ECR plasma.

As discussed above, Yamazaki fails to teach or suggest treating an inner surface of a tubular article's lumen with ECR plasma followed by coating the treated surface -- features recited in claim 1 as well as independent claims 21-24 and 26-28. Further, Williams, which is generally directed to forming a confluent layer of endothelial cell over a polymeric substrate functionalized by exposure to a nitrogen-containing plasma, does not teach utilizing an ECR plasma for functionalizing the surface. Likewise, Narayanan does not teach utilizing an ECR plasma for treating a surface, but rather describes treating polymeric surfaces with a radiofrequency generated plasma. Similarly, Makker employs a radiofrequency generated plasma, rather than an ECR plasma, to treat a polymeric surface. Thus, claims 21-24 and 26-28 are patentable over the cited art.

Claim 33

The Office Action does not address the patentability of claim 33. This claim recites a method of treating an inner wall of an electrically non-conducting lumen by placing a selected portion of the lumen in a treatment zone, and applying a magnetic field having a selected strength to that zone. A gas is introduced into the lumen within the selected portion so as to be in contact with the inner wall of that portion, and is irradiated with electromagnetic radiation having a frequency that is selected to be substantially equal to electron cyclotron frequency at the selected magnetic field strength so as to ionize the gas and create a plasma zone with the selected portion for treating the inner wall of the lumen.

As discussed in detail above, the cited references, neither individually nor in combination, teach or suggest treating an inner wall of a tubular article's lumen with an ECR plasma. In other words, these references fail to teach or suggest at least one material feature of claim 33. Accordingly, allowance of claim 33 is respectfully requested.

New Claims

New claims 51 depends on claim 33 and further recites coating the treated inner wall of the lumen with a selected material. And claim 52 depends on claim 51 and further recites flowing a solution of a bioactive material through the treated lumen so as to coat the lumen's surface. As discussed above, claim 33 is patentable, and hence so are claims 51 and 52.

Independent claim 53 recites a method for selectively treating an internal surface of a tubular article having a lumen by placing at least a portion of the tubular article in a treatment zone to which a magnetic field is applied. A gas is introduced into the article's lumen so as to generate an internal pressure within the tubular portion that is different than an external pressure to which an outer surface of that portion is exposed. The tubular portion is then irradiated with electromagnetic radiation having a frequency that is substantially equal to the electron cyclotron frequency at the magnetic field strength so as to generate a plasma within the lumen portion for treating thereof. Meanwhile, the external pressure inhibits formation of a plasma in proximity of the outer surface. The treated lumen surface is then coated with a selected material.

None of the cited references teaches or suggest such a selective exposure of a tubular article's lumen to an ECR plasma while generating a sufficient pressure differential between the lumen and an external environment to which the article's outer surface is exposed so as to inhibit plasma formation in the vicinity of the outer surface.

Independent new claim 54 recites a method of selectively treating an outer surface of a tubular article having a lumen by placing at least a portion of the article in a treatment zone containing a gas at a selected pressure such that an outer surface of at least a portion of the article is exposed to the gas, and causing an internal pressure within the article's lumen to be different than the treatment zone pressure. An ECR plasma is generated within the treatment zone so as to treat the outer surface by exposure to the plasma while the lumen's internal pressure inhibits formation of a plasma within the lumen. This is followed by coating the treated outer surface with a selected material.

None of the cited references teaches or suggests such a selective treatment and coating of a tubular article's surface while ensuring that the article's internal pressure is selected so as to inhibit plasma formation within the lumen.

Thus, independent claims 53 and 54, and claims 55-58 that depend on claim 54, are patentable over the cited art.

CONCLUSION

In view of the above amendments and remarks, Applicants respectfully request reconsideration and allowance of the application. Applicants invite the Examiner to call the undersigned at (617) 439-2514 if there are any remaining issues.

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